append in the footnote excerpts from the material emanating from professional sources.[4]

"Little comment need be made on this advertising; it speaks for itself. Plainly the sponsor intended to be understood as adopting as his own the quoted statements of the doctors and professional dispensers of the preparation. That these would be taken by the lay reader as unqualifiedly prescribing the use of Colusa oil in the treatment of acne and poison ivy or oak, admits of no fair doubt.[5] The term 'prescribe' is given the following definition by Webster: 'Med. To direct, designate, or order the use of, as a remedy.'[6] The word 'designate,' in turn, is defined as 'to mark out and make known; to point out; to indicate.' Neither logic nor fairness requires a narrower definition of the term when employed in flamboyant advertising like the present. The word 'prescribe' of course includes recommending and suggesting.

"Other points urged are unworthy of specific attention.

"Affirmed."

The individual defendant filed a petition for certiorari with the United States Supreme Court on November 17, 1949, and this petition was denied on January 9, 1950.

3062. Misbranding of Powdr X. U. S. v. Lafayette M. Gray (L. M. Gray and Powdr-X Co.). Plea of not guilty. Tried to the jury. Verdict of guilty on counts 1 and 3 and not guilty on count 2. Fine of $1,000 and costs. Judgment reversed by court of appeals and new trial ordered. Petition for certiorari denied by Supreme Court. Plea of nolo contendere. Fine, $1,000. (F. D. C. No. 21482. Sample Nos. 43748-H, 43981-H, 44462-H, 52670-H.)

INFORMATION FILED: July 31, 1947, District of Minnesota, against Lafayette M. Gray, trading as L. M. Gray and the Powdr-X Co., Minneapolis, Minn.

ALLEGED SHIPMENT: Between the approximate dates of December 4, 1945, and March 23, 1946, from the State of Minnesota into the States of California and Indiana.

LABEL, IN PART: "Powdr X * * * Contents Silicon Dioxide, Aluminum Oxide, Ferric Oxide, Calcium Oxide, Magnesium Oxide, Sodium Oxide."

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[4] "SUMMARY OF CLINICAL REPORTS ON 28 CASES—

"A doctor who owns a hospital in Texas reported under oath that in a clinic of 20 cases of psoriasis, '16 cleared of all lesions completely in 30 days—4 were 70% clear and continued treatment; that out of 40 cases of eczema all but three were cleared of all lesions in 3 weeks to a month with prognosis of the three good for recovery; that out of 11 cases of athlete's foot all, save one who did not return for treatment, were completely cured—8 to 14 days for acute cases and 3 weeks for chronic cases; that out of three cases of leg ulcers complete healing resulted in all 3 of the cases in a month; and in 8 cases of poison ivy or oak, complete cures were effected in an average of 5 days.' His report states, 'not in a single case of this clinical group did I meet with toxic bad effects . . . Intolerance or flare-ups . . . Colusa may be used near the eyes without danger . . . it relieves itching quickly. A little of the oil covers large areas. It is non-irritating. Soothing to raw and denuded lesions and affected areas. Easily massaged into the skin.'

"Two other doctors make similar glowing clinic reports—one, a United States Government health physician reporting on 25 cases, and the other a Mexican Government health physician reporting on 43 cases.

"THOUSANDS OF DOCTORS ARE COLUSA CUTOMERS

EXCERPTS FROM A FEW OF THEIR REPORTS—

"New York—Dr. C.—practiced 10 years. . . . (Case b) 'Poison ivy on entire body. Intense itching and swelling, itching stopped almost immediately on application of Colusa prod. and had entirely cleared in 5 days.' . . .

"Ohio—Dr. H.—practiced 44 years . . . (Case b) 'acne, 3 cases, all improving.'

"EXCERPTS FROM REPORTS BY DRUGGISTS—

"Nebraska druggist—99% pleased customers. Stubborn cases: . . . 'Worked wonderfully acne.'"

[5] In the stipulation of facts made on trial the appellants impliedly concede that the advertising prescribed the use of the oil for the four diseases mentioned on the label. Colgrove appears to make a like concession in his oral testimony. There is no valid ground for the attempts to distinguish between the language employed in references to these four diseases and that relating to others referred to by the doctors and druggists.

[6] Webster's New International Dictionary, 1937 Ed. Unabridged.

NATURE OF CHARGE: Count 1. Misbranding, Section 502 (a), the statement "In fact it is an ointment that is splendid for almost any infection, abrasions, or ulcers," appearing in a letter addressed to the consignee of the article, was false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of almost any infection, abrasions, and ulcers; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice; and Section 502 (f) (1), the labeling of the article bore no directions for use.

Count 2. Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

Count 3. Misbranding, Section 502 (a), the statements "We have a very good reason for expecting Powdr-X to correct ulcers of the stomach * * * Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days," appearing in a letter addressed to the consignee, were false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of ulcers of the stomach; and, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice.

Count 4. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the cure, mitigation, and treatment of pernicious anemia, athlete's foot, cancer, colitis—mucous and ulcerative, enlarged glands causing stoppage of fluid, gall bladder infection, general debility, Hodgkin's disease, hyperacidity, osteomyelitis, piles (bleeding), hemorrhoids, poison ivy, poison oak, rheumatism other than arthritis, sinus infection, trench feet, trench mouth, tuberculosis of the bone, tuberculosis (pulmonary), stomach ulcers, varicose veins, and any and all cases of infection, which were the conditions for which the article was prescribed, recommended, and suggested in its advertising, disseminated and sponsored by and on behalf of its manufacturer and packer; and, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice.

DISPOSITION: A motion dated October 29, 1947, to dismiss the information on the ground that more than one offense was charged in each count, was filed on behalf of the defendant. Another motion dated October 29, 1947, for a bill of particulars in respect to counts 2 and 4 of the information was filed also on behalf of the defendant, requesting that the dates of shipment be alleged definitely and with particularity; that the name of the "manufacturer" and the name of the "packer" referred to in count 4 be given; and that certain details with respect to the "advertising" referred to in count 4 be specified.

On January 24, 1948, the court entered an order which denied the motions but which provided that the information be amended by the addition, at the end of each count, of the words "It being the intent and purpose of the plaintiff to charge hereunder, only one interstate shipment and offense under the Food, Drug, and Cosmetic Act," and by the change of the phrase "sponsored by and on behalf of its manufacturer and packer," set forth in Section 502 (f) (1), under count 4, so that it would read "and sponsored by and on behalf of defendant as manufacturer and packer aforesaid."

Thereafter, count 4 of the information was dismissed on the ground that subsequent investigation revealed that the interstate shipment was made more than three years prior to the filing of the information, so that the statute of limitation operated as a bar. A plea of not guilty was entered on behalf of the defendant on March 8, 1948, and on March 9, 1948, the case came on for trial before the court and jury. The trial was concluded on March 27, 1948, with the return by the jury of the following verdicts: Count 1, guilty of misbranding by reason of a label which was false and misleading, not guilty of failure to designate *Powdr X* as pumice, and not guilty as to inadequate directions; count 2, guilty of failure to designate *Powdr X* as pumice and not guilty as to inadequate directions; and count 3, guilty of misbranding by reason of a label which was false and misleading, not guilty of failure to designate *Powdr X* as pumice, and not guilty as to inadequate directions.

Subsequently, a motion for a judgment of acquittal, or, in the alternative, for a new trial, was filed on behalf of the defendant. At the opening of the hearing on the motion, the defendant withdrew its motion for a new trial, and, consequently, the motion for judgment of acquittal was the only matter involved. On May 11, 1948, the following decision in denial of the motion for judgment of acquittal was handed down:

NORDBYE, *District Judge:* "The above cause came before the Court on defendant's motion for judgment of acquittal, or, in the alternative, for a new trial. However, at the opening of the hearing on the motion, defendant withdrew its motion for a new trial, and therefore the motion for judgment of acquittal is the only matter which was presented.

"Defendant's motion for judgment is based on two grounds: (1) That the jury found defendant guilty only of offenses in support of which there was no evidence and with which he was not charged; and (2) there was no evidence to support a finding that the labeling was false and misleading because there was no evidence to support the finding that Powdr-X was not efficacious.

"The first ground is directed to the contention that, according to the form of the verdict submitted to, and returned by, the jury, the defendant was found guilty of offenses with which he was not charged in the information and in support of which there was no evidence at the trial. Defendant points out that, in Count I of the information, he was charged with misbranding within the meaning of 21 U. S. C. A. § 352 (a), in that the statement in the letter addressed to the consignee and accompanying the drug, 'In fact it is an ointment that is splendid for almost any infection, abrasions, or ulcers' was false and misleading in this, that said statement represented and suggested that said drug would be efficacious in the cure, mitigation and treatment of almost any infection, abrasions, or ulcers, whereas, in fact and in truth, said drug would not be efficacious in the cure, mitigation and treatment of almost any infection, abrasions, or ulcers; and that, in Count III of the information, defendant was charged with misbranding within the meaning of 21 U. S. C. A. § 352 (a) in that, accompanying said drug which was caused to be introduced into interstate commerce, there was a letter addressed to the consignee in which certain statements appeared, and the information sets forth that the statements 'We have a very good reason for expecting Powdr-X to correct ulcers of the stomach * * *. Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days' were false and misleading in this, that said statements represented and suggested that said drug would be efficacious in the cure, mitigation and treatment of ulcers of the stomach.

"The defendant then points out that the form of the verdicts as submitted to the jury and as returned by the jury as to Counts I and III, finding the defendant guilty of misbranding, reads as follows:

> We, the jury in the above-entitled action, find the defendant, as charged in the * * * information, guilty of misbranding by introducing into interstate commerce a drug, to wit, Powdr-X, with a label which was false and misleading: * * *

"Defendant's position is that he was not charged with introducing into interstate commerce a drug with a *label* which was false and misleading, but rather

that the *labeling* within the meaning of the Act was false and misleading. But a consideration of the entire situation would indicate that the motion for judgment on this ground seems to be extremely hypercritical and captious and must be rejected. Section 352, 21 U. S. C. A., reads:

A drug or device shall be deemed to be misbranded—

False or misleading label

(a) If its labeling is false or misleading in any particular.

Section 321 (m), Title 21 U. S. C. A., reads:

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The Court in its charge went into considerable detail in setting forth the respective counts in the information, and specifically directed the jury's attention to the letter which was said to be sent to the consignee referred to in Count I and the contention of the Government that this letter was a labeling of the drug within the meaning of the law. The same detailed statement was made with reference to the letter sent to the consignee named in Count III, and which letter the Government contended was a labeling of the drug within the meaning of the law. As to both the letters in the Feltenberger and Evans counts, the Court stated:

I charge you that if they did accompany the shipments, in light of the instructions I have given you, then such letters constituted labeling within the meaning of the law, even though the letters were not physically attached to the cartons as labels. Consequently, if you find that Powdr-X was a drug within the meaning of the law, and if you further find that there was a labeling of the drug by the defendant within the instructions and definitions that I have given to you, then you will determine whether or not the labeling was false and misleading.

"In drawing the verdicts, the Court used the term 'with a label which was false and misleading' instead of 'with a labeling which was false and misleading.' But, obviously, in light of the Court's instructions, there was no possibility that the jury did not understand that when the Court used the term 'label,' it was with reference to the letter which accompanied the shipment and which would constitute a labeling under the Act if it accompanied the shipment, as explained in the Court's instructions. Strictly speaking, the term 'labeling' would have been more appropriate than the term 'label,' but, in that connection, reference may be made to the Act itself, which appears to use the term 'label' and 'labeling' interchangeably; that is, in the quoted part of Section 352, it will be noted that following the statement, 'A drug or device shall be deemed to be misbranded' appears a heading entitled 'False or misleading label,' followed by '(a) If its labeling is false or misleading in any particular.' And, to all intent and purpose, under Section 321 (m) any written matter accompanying the drug does become a 'label' within the meaning of the law.

"Strangely enough, the only one who was in any way concerned with the form of the verdicts in this regard was the Assistant United States Attorney, who, after the Court had instructed the jury, called to the Court's attention the use of the term 'label' in the verdicts instead of the term 'labeling' as follows:

When I mentioned the matter of the label and the labeling at the conclusion of your charge I didn't have in mind the significance of it as it was brought to my attention by Mr. Goding; and we had the reporter read back what was said to the jury with respect to these forms of verdict and we got copies of the forms which were placed with the jury. It appears that on the one, for instance, the Feltenberger, it should have read; "To wit, Powdr-X, with labeling," instead of "with a label which was false and misleading."

The Assistant United States Attorney suggested that a corrected form of verdict be submitted to the jury and that the jury be called back for that purpose. Counsel for the defendant, however, strenuously objected to the calling back of the jury as suggested by the Assistant United States Attorney, stating, among other things,

No objection was made to those forms of verdict by the Government and no exception to those forms of verdict was taken by the Government before the jury retired. It would be highly improper and without precedent whatever to now interfere with the deliberations of the jury for the purpose of giving them any other forms of verdict.

And after a colloquy between counsel, the Court stated to the attorney for the Government:

The jury can't possibly be misled by the form of verdict in so far as the term "label" is concerned. Certainly I went into great detail, and at your suggestion, after the jury was charged, called their attention to the fact that the labeling was not only the labeling which appeared by way of letter which accompanied the shipment, but was that which was attached to the carton. * * * Of course, my only purpose in using it was to identify the count—the various misbranding counts that appear in the respective counts, so that they could intelligently follow the instructions and intelligently return a verdict.

And at the close of the charge to the jury, after the Assistant United States Attorney had made some reference to the use of the term 'label' instead of the term 'labeling,' the Court stated to the jury:

Counsel have discussed some matters that possibly I should call to your attention. I instructed you regarding the question as to whether or not these letters would constitute labeling within the meaning of the law. Of course, if they are labeling within the meaning of the law that does not mean that the label on the carton itself is not a labeling. It would simply mean that in addition to the label on the carton you would have the labeling that may appear in the letters. I don't believe there should be any confusion in your mind about that, but in the event there is I hasten to clarify it.

"Certainly, there can be no possible question but that the jury understood that, when the Court used the term 'label' in the forms of verdict submitted to them, it was referring to the letters which had been written by the defendant containing the statements regarding the efficacy of Powdr-X. Days were spent in Court in endeavoring to decide whether or not the representations or statements made in these letters constituted a labeling which was false and misleading. In the main, the verdicts were drawn with considerable care so that the jury would be able to pass upon each phase of misbranding as set forth in the first, second and third counts. Granted that the word 'labeling' rather than the word 'label' would have been the better term to have used in the forms of verdict submitted, but to suggest now that the forms of verdict, to which no objection was made by the defendant and which the defendant in fact approved by his objection to any change therein, constituted any prejudice to the defendant is a sheer afterthought and seems highly hypercritical. There was no contention that the label affixed to the carton itself contained any false and misleading statements. The only label or labeling which contained any false and misleading statements, according to the Government's evidence was that which was set forth in the letters to Feltenberger and Evans. Obviously, therefore, the jury could not have been misled by the wording used in the forms of verdict submitted. When they returned verdicts of guilty as to misbranding by reason of a false and misleading label, they concluded that the Feltenberger and Evans letters constituted a labeling within the meaning of the law and that defendant's representations therein as to the medicinal value of Powdr-X were untrue under the evidence. The Court is clear that the first point urged in support of the motion for judgment of acquittal is utterly devoid of merit.

"The second ground urged in support of the motion for acquittal is apparently predicated on the theory that the medical experts produced by the Government either directly or indirectly conceded that they were assuming that Powdr-X was a pumice when they expressed an opinion that the drug had no therapeutic value. The defendant contends, therefore, that the jury having found that Powdr-X was not a pumice, it must necessarily follow that the opinions of the Government experts fall. The record indicates that the hypothetical question submitted to the Government medical experts did not incorporate an assumption that Powdr-X was a pumice, but rather that it was a volcanic ash. The question as propounded to the Government experts was substantially as follows:

Q. Doctor, I will ask you to assume that Powdr-X has been established as a volcanic ash, that is, that it is a volcanic glassy material, very finely divided, that the further testimony introduced into court shows that 5 grams of Powdr-X neutralizes 2 cc of 1/10 normal hydrochloric acid; that Powdr-X is not soluble in water and only slightly soluble in acid, and that as to the antiseptic qualities of Powdr-X it is inert to germs and bacteria. Now, assuming these facts I will ask you from your knowledge and experience as a physician, have you any opinion as to whether or not such a product, that is, Powdr-X, can be used in the treatment, that is, in the cure, mitigation, and treatment of infections or abrasions or external ulcers?

True, on cross-examination, and perhaps on direct, some of the Government experts admitted that they assumed in giving their opinions that Powdr-X was a pumice or its equivalent, volcanic ash. But it must be evident that the opinions of the doctors as to the efficacy of Powdr-X were based on the physical

and chemical properties thereof and not on the common, the mineralogical, or the geological name which might properly be ascribed to the drug itself. Whether Powdr-X is correctly designated as a pumice, volcanic ash, volcanic tuff, or a kaolin does not necessarily have any bearing on its efficacy or its therapeutic value in the treatment of the ailments and diseases referred to in the hypothetical questions. Rather, it is the physical and chemical properties of the drug which are the factors which would control. There was a great deal of testimony offered as to whether Powdr-X should have been labeled as a pumice, as that term is found in the National Formulary, and as to whether pumice was the common name for the substance. But whatever conflict there may have been on that issue, the evidence overwhelmingly indicated that the substance known herein as Powdr-X was originally of volcanic origin. Some of the Government witnesses referred to it as pumice or a volcanic ash, while some of the defendant's witnesses contended that it was more properly designated as a volcanic tuff. But whatever it might be called, it had certain chemical and physical properties which were controlling as the basis for the opinion given by the medical experts. All of the testimony, therefore, presented a fact question for the jury as to whether or not the substance known as Powdr-X had the medicinal properties which the defendant represented it had in the letters that he wrote to Mrs. Feltenberger and Mr. Evans. The jury found by its verdicts that the statements contained in these letters were false and misleading and there was ample evidence to sustain that finding. Moreover, the mere fact that the jury concluded that the Government had not sustained the burden of proof in establishing beyond a reasonable doubt that Powdr-X was a pumice does not mean that they concluded that it was not a volcanic ash or volcanic tuff, or a substance substantially the same or very similar to pumice. They may well have concluded that it was originally a volcanic ash, or a pumice, but, due to the effects of water erosion and other phenomena of nature, it had acquired certain clay-like properties and therefore could not strictly be classified as a pumice. But, whatever may have prompted the jury to reach the conclusion that it did, there is no inconsistency between its findings on that charge of misbranding, that is, the question as to whether or not the Powdr-X was a pumice, and its finding with reference to the charge of misbranding as to the truth of the representations made regarding the curative properties of this drug. And, whether the jury's findings of not guilty as to the other charges of misbranding was the result of compromise, mistake, or honest conviction, is obviously not for this Court to determine. The jury was required to make a finding as to whether or not Powdr-X had the curative properties which would enable it to alleviate and heal abrasions, cuts and ulcers. Evidently, the jury found that Powdr-X was without any curative properties in the particulars represented by the defendant, and that therefore the labeling was false and misleading. Any doubt that the jury may have had as to whether Powdr-X was a pumice under the evidence does not in any way militate against the soundness of its verdict in determining that the product was devoid of any medicinal value.

"As to whether or not a verdict should be set aside on the grounds of inconsistency of the findings on the several counts, see Dunn v. United States, 284 U. S. 390. While that case referred to the alleged inconsistency as among the several counts, and here we have an alleged inconsistency between the findings of misbranding included in one count, it would seem that the views of the Supreme Court therein are persuasive in the instant situation. Moreover, here we have no repugnancy in the jury's findings on the several charges of misbranding.

"The motion for judgment of acquittal, therefore, must be and is in all things denied. An exception is allowed."

On June 1, 1948, the court imposed a fine of $1,000, plus costs (the amount of costs to be determined later), against the defendant. The defendant filed an appeal with the United States Court of Appeals for the Eighth Circuit, on June 17, 1948. On July 16, 1948, on motion of the Government's attorney, the court, after hearing, entered an order taxing costs in the amount of $1,000. The court originally had approved costs in the amount of $1,633.90, but after hearing, during which the defendant contended that this amount should be reduced because the Government had not been successful in sustain-

ing all its charges, the court reduced the amount of costs to $1,000. (However, when the case was ultimately disposed of, no costs were imposed.)

On April 18, 1949, after consideration of the briefs and arguments of counsel, the United States Court of Appeals for the Eighth Circuit handed down the following opinion:

WOODROUGH, *Circuit Judge:* "The appellant was convicted and sentenced to pay a fine of one thousand dollars and costs for introducing into interstate commerce a certain drug called Powdr-X contained in packages and misbranded, in violation of the Federal Food, Drug and Cosmetic Act, § 301 (a) et seq., 21 U. S. C. A. 331 (a) et seq. The information against him contained four counts but the jury found him not guilty on count 2, and count 4 was dismissed during the trial. The judgment from which he appeals was entered upon the jury verdicts on the remaining counts of the information numbered one and three. Each of these counts was predicated upon one of the two shipments of packages of the drug made by appellant at Minneapolis, Minnesota; one shipment on December 6, 1945, to Mrs. H. Feltenberger at Culver City, Calif. (first count), and the other on March 23, 1946, to Ira J. Evans at North El Monte, Calif. (third count). The charge was to the effect that in each of the shipments the drug was misbranded in violation of the Act; (1) that the label upon each of the immediate containers was as follows:

"POWDR
X
Net Weight 8 oz.
CONTENTS
Silicon Dioxide, Aluminum Oxide,
Ferric Oxide, Calcium Oxide,
Magnesium Oxide, Sodium Oxide.
L. M. Gray, National Distributor
3856 Chicago Avenue
Minneapolis, Minn.
Phone Colfax 8295."

(2) that the appellant accompanied each shipment with a letter intended to be used together with the drug and constituting a labeling thereof, which letter he mailed to the consignee on the same day he made the shipment. In one of the letters it was stated that the drug was 'splendid for almost any infection, abrasion or ulcers' (first count), and in the other that 'We have good reason for expecting Powdr-X to correct ulcers of the stomach * * *' 'Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days,' which statements were false and misleading and in truth said drug would not be efficacious as stated; (3) that the drug was not designated by a name recognized in an official compendium and its label failed to bear the common or usual name of the drug, to-wit, pumice; (4)[1] the labeling failed to bear adequate directions for use, to-wit, there were no directions for use.

"Before entering his plea appellant moved to dismiss the information on the ground that each of the counts was duplicitous in that each attempted to charge more than one offense denounced by the Act, because each count[2] charged against him conduct alleged to be in violation of 21 U. S. C. A. 352 (a)[3] and conduct alleged to be in violation of 21 U. S. C. A. 352 (e)[4] and conduct alleged to be in violation of 21 U. S. C. A. 352 (f).[5]

"It was argued for the motion and is reiterated here that these three kinds of conduct connected with the shipment of drugs in interstate commerce, to-wit, (1) accompanying the shipment with a letter containing false statements;

[1] Count three did not include this specification (4) contained in count one.
[2] Except as above noted.
[3] Section 352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.
[4] (e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; * * *.
[5] (f) Unless its labeling bears (1) adequate directions for use.

(2) failing to put the true name of the drug on its 'label,' and (3) failing to include directions for use in its 'labeling,' should be deemed separate offenses and pleaded in separate counts under 18 U. S. C. A. 557 and Rule 8 (a) of F. R. C. P. It is stressed that the Act makes clear and positive distinction between conduct in respect to what the Act defines as the 'label' on the package of the drug and in respect to what it defines as the 'labeling' of the drug. 21 U. S. C. A. § 321 (k) provides that 'the term "label" means a display of written, printed or graphic matter upon the immediate container of any article; * * *,' and 21 U. S. C. A. § 321 (m) says that 'The term "labeling" means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The Act makes 'labeling' the broadly inclusive term and 'label' is narrowly confined to what is put on the immediate container. It is contended that writing and mailing a letter containing false statements about the drug is conduct so different in kind from failing to put required matter in its label or failing to put required instructions for use in either the letter or the label that the inclusion of charges of the three sorts of misconduct in each count made each count duplicitous.

"The trial court after consideration of the motion and argument, concluded that the charge in each count was single and not duplicitous in that the offense charged in each count was the introducing and delivering for shipment in interstate commerce of a misbranded article, in violation of 21 U. S. C. A. § 331 (a), which prohibits the introduction or delivery for introduction into interstate commerce of 'any * * * drug that is * * * misbranded,' under penalties provided in § 333 (a). It deemed the several acts and omissions charged against appellant to be specifications of the ways in which that offense was committed by him. We find no error in that ruling.

"But the court recognized that the offense in each count might be established under the information by proof of either one or all of the ways in which misbranding was charged to have been accomplished and it suggested to the prosecutor to amend the information by adding to it at the foot of each count the following: 'It being the intent and purpose of the plaintiff to charge hereunder only one interstate shipment and offense under the Food, Drug and Cosmetic Act.'

"The amendment having been made the motion was treated as being directed against the amended information and was denied, a plea of not guilty as to each count was entered and the trial proceeded before the court and jury over a period of 16 days. It was not disputed that the appellant had made the two shipments of the drug, each including a number of packages of the Powdr-X produced by grinding up a certain mineral substance found in volcanic formation on a ranch property in Colorado, nor that the packages shipped bore the label described in the information, nor that appellant caused the two shipments to be accompanied by the described letters mailed by him to the respective consignees, but the testimony of lay and expert witnesses on the questions as to what Powdr-X really was and whether or not it was pumice as charged and whether or not it had therapeutic capacities as represented in the letters was very voluminous and contradictory in respect to the inferences to be drawn from it.

"At the conclusion of its instructions to the jury the court delivered to the jury forms of verdict with blank spaces which the jury was directed to fill in with the words 'guilty' or 'not guilty,' according to the findings arrived at. The forms had been prepared by the prosecution and appear not to have been exhibited to appellant's counsel, or discussed before their delivery to the jury. There was one form for each of the three counts submitted to the jury but each form required the jury to make and declare more than one determination of 'guilty' or 'not guilty' upon each of the three counts submitted to it. Responding to count one, the form filled in by the jury with the words 'guilty' and 'not guilty' and returned into court as the jury's verdict on that count reads as follows:

Verdict as to First Count of Information (Feltenberger)

We, the jury in the above entitled action, find the defendant, as charged in the first count of the Information . . . guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, with a label which was false and misleading; not guilty of misbranding by introducing a drug, to-wit, Powdr-X, in interstate commerce which was not designated solely by a name registered in an official compendium and that its label failed to bear the common name of the drug, to-wit, pumice; not guilty

of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, which failed to bear adequate directions for use. (Feltenberger)

Dated this 27th day of March, 1948.

Richard A. Fancher
Foreman [6]

"As shown on the face of this verdict the jury undertook to make special declarations by use of the words 'guilty' or 'not guilty' in respect to particulars of misbranding described by paraphrases of parts of the information in the verdict-forms but the only matter in respect to which the jury found the appellant guilty was 'of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, with a label which was false and misleading.' Responding specially to other particulars of the charges paraphrased in the verdict-forms, the jury wrote in the words 'not guilty.'

"The record shows that after the instructed jury had been deliberating for some hours without coming to agreement the prosecuting attorney in the presence of appellant's counsel indicated to the trial judge in chambers that mistakes had been made in the wording of the forms of the verdicts delivered to the jury which they were directed to fill out. The prosecutor used the verdict-form applicable to the first count for illustration and pointed out to the court that the wording of the form related the declaration of 'guilty' or 'not guilty' which the jury might write in the first blank space in the form, to 'a label' that was false instead of to 'labeling that was false' but there was no formal request or motion to recall the jury and make the correction. There was extended discussion in chambers between counsel on both sides and the judge, but it resulted in no action taken concerning the verdict-forms. The court indicated it was satisfied with the verdict-forms. Later the jury returned into court requesting further instructions but the matter of the verdict-forms was not then referred to. On the coming in of the verdicts the court entered judgment: 'It is adjudged that defendant has been convicted upon verdicts of guilty of the offense of misbranding by introducing into interstate commerce a drug, to-wit: Powdr-X, with a label which was false and misleading as charged in counts 1 and 3 of the information * * *,' and sentence was imposed as stated.

"At the conclusion of all the evidence the appellant had moved for verdict of acquittal and promptly after the verdict had been returned against him he again moved for judgment of acquittal. The motions were denied and he contends here that the rulings were erroneous.

"(1) In the first place he contends that in this criminal prosecution there was no power or discretion in the court to require the jury to return verdicts which were in the nature of the special interrogatories and answers thereto which are permissible in civil actions but which have no place in criminal procedure. His position is that a count in a criminal information must state only one offense; that the only permissible plea to it is guilty or not guilty or nolo contendere, and that upon the plea of not guilty the only issue for the jury joined by the charge of the count and the plea is the general issue of 'guilty' or 'not guilty,' and that the jury must be required to respond to that issue by a general verdict. His counsel took timely exception to the action of the court in submitting verdict-forms to the jury requiring multiple responses to each count on the ground that the forms 'required or permitted the jury to make a finding of guilty or not guilty three times in respect to count one, twice in respect to count two and twice in respect to count three,' and 'there is no authority by statute, by Federal Rules of Criminal Procedure, or by precedent of decision to permit such verdicts to be submitted to the jury for the purpose of returning verdicts in any criminal case; and upon the further ground that it in effect gives the jury an opportunity to arrive at some sort of a compromise which they might not arrive at if they were given verdicts which required them to find only once as to each of the three counts whether the defendant is guilty or not guilty.'

"In the argument here appellant's counsel again asserts that after diligent search he has found 'no statute, Rule of Criminal Procedure or precedent of decision' sanctioning the delivery of such a form of verdict to the jury for the purpose of returning their verdict in a criminal case or the requirement that the jury respond three times 'guilty' or 'not guilty' to one count of a criminal information. The prosecutor cites none and we find none. We think, as stated

[6] The form of verdict on count 3 was the same omitting the last not guilty finding.

by the court in *Anderson* v. *United States*, 273 F. 677, that 'it is not the practice of the federal courts in criminal cases to call for special verdicts.' c. f. *United States* v. *Noble*, 155 F. 2d 315. And we are constrained to conclude that the delivery of these forms to the jury and the direction to fill them out with several declarations of guilty or not guilty as to each count present an innovation in American criminal practice. It would serve no purpose to review the discussions of the courts and law writers concerning the use of special interrogatory and answer verdicts in civil actions. There are many well known arguments for and against the practice but no one doubts that the question whether it should or should not be followed is a question of due process and is important and far reaching. The vesting of discretion in the trial court to apply the practice in civil actions ultimately achieved by Rule 49 of the new Rules of Civil Procedure however is no indication of authority to use it in criminal trials. In such trials the practice has been settled time out of mind to charge but one crime in one count, to accept but one general plea to it and to call upon the jury to make but one general response, guilty or not guilty. Such established procedure was obviously departed from here over appellant's objection and it may not be held that such a departure did not affect appellant's substantial right to be tried according to law. It is not the function of the courts subordinate to the Supreme Court to introduce innovations of criminal procedure. The action of the court requiring the special verdicts duly excepted to by appellant constituted error.

"(2) Appellant also contends here, as he did upon his motion for acquittal made after verdict in the trial court, that the verdicts which purport to find him 'guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X with a label which was false and misleading' were fatally defective and insufficient to support a judgment of conviction or sentence against him because the information did not charge him with that offense and there was no substantial evidence that he committed it.

"The record, considered with the provisions of the Act, has convinced that this contention for appellant is sound and that the verdicts are fatally defective. It is clear that the Act makes it a punishable offense to introduce a drug into interstate commerce 'with a label which is false and misleading.' 21 U. S. C. A. § 331 (a) prohibits such introduction of a drug that is misbranded; 21 U. S. C. A. § 352 (a) says that a drug is misbranded if its 'labeling' is false or misleading in any particular, and 21 U. S. C. A. § 321 (m) says that 'the term "labeling" means "all labels"' as well as other things. But in this information the only specification against the label with which the Powdr-X drug was shipped was that the label failed to bear the common or usual name of the drug. Although the label was set out in full in the information, it was not stated that the label was false or misleading and there was no proof that it was. It is beyond argument that a man can not, under the Fifth and Sixth Amendments, be convicted and sentenced for an offense not charged and not proven against him, and that is the situation in which this appellant stands upon the record before us. As succinctly stated by the Supreme Court a hundred and fifty years ago, 'A verdict is bad if it varies from the issue in a substantial matter,' *Patterson* v. *United States*, 2 Wheaton 221.

"It is argued for the government in support of the judgment that we may regard the opening words of the verdicts, 'We, the jury find the defendant as charged in the first count of the information guilty of misbranding,' to be a general verdict of guilty on the first count and may treat the remaining parts of the verdicts as surplusage. That is to say we should treat as surplusage not only the jury's specific finding that defendant was guilty of the certain clearly stated offense denounced by the Act in respect to 'a label which was false,' but also the two instances in the same verdict in which the jury says it finds the defendant 'not guilty of misbranding.' But we must decline to indulge in such unreasonable straining at the record. It is evident from the record that the jury was not required to and did not intend to render a general verdict on any count of the information here. It was erroneously required to render verdicts in the nature of special verdicts in answer to particulars of the information, and regardless of abstractions about the merits and demerits of that practice in general it is obvious that in this case it was the attempt to apply a sort of special verdict practice that resulted in the void verdicts. None of the numerous criminal cases in which surplusage added to general verdicts of guilty has been deemed harmless can be held to be applicable to the situation

here presented. Cf. *Statler* v. *United States*, 157 U. S. 277; *Patterson* v. *United States*, 2 Wheaton 221; *Samlin* v. *United States*, 278 Fed. 170.

"Here the jury did not mistakenly add inconsequential matter to a general verdict or anything that can fairly be called surplusage. It complied with the direction given by the court to make special response to special matter stated in paraphrases submitted to them. In consequence its verdict 'varied from the issue' and was 'bad.'

"It is further contended for the government that the only fair inference to be drawn from a reading of the whole record of the evidence, the proceedings and the instructions, together with the verdict, is that the jury must have meant that the statements in appellant's letters about the therapeutic efficacy of his drug, which were its labeling as defined by the Act, were false. We recognize that a verdict even in a criminal case need not be avoided because of slight or inconsequential ambiguity contained in it where that is dispelled entirely and the import is rendered clear and certain by the context of the record of which it forms a part. But the voluminous record here does not present any basis other than mere speculation to conclude that the jury meant to say that the appellant was guilty of anything other than the offense of which they found him guilty. Although the record shows that a great amount of testimony was directed to the issue of false labeling in the letters and we find sufficient evidence to justify a finding if one had been made that there was such false labeling, the fact remains that there was a dispute on that issue of the kind that can only be settled by a jury under our system. That there were differences among the jurors is manifest from the fact that they came into court asking to have their 'memories refreshed' as to testimony and as to the instructions and were out altogether twenty-seven and a half hours. But if their concurrence finally arrived at was in respect to the labeling found in the letters there was no place in the special forms they were required to fill out to so indicate. They did not so indicate. The conclusion is inescapable that the error in the proceeding was not a mistake in wording or phrasing made by laymen on the jury whose true intent may be verified by reference to other parts of the record. The fatal error was committed in requiring the jury to fill out a special form whose paraphrases included no reference to letters mailed by appellant and which did not permit the jury to make any response to the issue whether false labeling by means of the letters had or had not been committed by the appellant. It can only be concluded that the judgment of conviction is not supported by the verdicts.

"It is also argued that the appellant should be deemed to have waived the defects in the forms of verdict because he did not point them out to the court at the time the court delivered them to the jury. But the record shows that the court's attention was called to the defects both before the forms went to the jury and afterwards before the verdicts were arrived at. The court stated, 'The jury can't possibly be misled by the form of verdict in so far as the term "label" is concerned.' 'I can't conceive that there is anything but a rather captious objection to the word "label" as I used it in the verdict.' As this court's study of the record has led to contrary conclusions and to holding that in consequence of the defects in the forms it has resulted that there was no verdict of guilty of false labeling within the charge of the information, the onus of the outcome may not be shifted to the appellant. He was put in jeopardy on the charges of the several counts of the information and the jury was discharged without having rendered verdicts of guilty responding to the charges and he is therefore entitled to have the judgment against him avoided.

"Reversed and remanded with direction to set aside the judgment and discharge the accused."

A petition for rehearing was filed on behalf of the Government, with the United States Court of Appeals for the Eighth Circuit, and on June 6, 1949, an order was entered by that court denying the petition. The order provided, however, that the opinion filed April 18, 1949, be corrected by striking therefrom the last paragraph reading "reversed and remanded with directions to set aside the judgment and discharge the accused" and that there be substituted in lieu thereof the following "reversed and remanded with directions to set aside the judgment and grant a new trial." The order also provided that the judg-

ment of the court of appeals entered in pursuance of the opinion filed April 18, 1949, be corrected accordingly.

Following the entry of the order of June 6, 1949, a petition for rehearing was filed on behalf of the defendant, and on July 14, 1949, such petition was denied. A petition for a writ of certiorari was then filed by the defendant with the United States Supreme Court, and was denied by that court on October 17, 1949.

A motion for dismissal of the informaton was filed in the United States District Court for the District of Minnesota on March 1, 1950, and on March 9, 1950, the following decision was handed down by that court:

NORDBYE, *District Judge:* "This cause comes before the Court on defendant's notice of motion to dismiss each of the four counts in the information on the grounds set forth in said notice.

"This motion to dismiss is bottomed upon the contention that if defendant is tried again on the offenses alleged in the several counts of the information, he would be put in jeopardy a second time for the same offenses in violation of his rights under the Fifth Amendment to the Constitution of the United States. In that Count IV has already been dismissed by this Court because the offense charged therein has been barred by the statute of limitations, it follows that that count is no longer included in the information. Moreover, as to Count II, regardless of the alleged irregularity or innovation in the form of the verdict returned by the jury, it is my opinion that the verdict was one of not guilty and should be so considered. Consequently, that count will not be before the Court on any new trial to be had herein. That leaves Counts I and III to be considered on defendant's motion for a dismissal. In view of the Court's determination that a new trial may be had as to certain specifications of misbranding alleged in these counts, the following observations may be made.

"The Court of Appeals in its mandate directed this Court to set aside the judgment entered herein and grant a new trial. Defendant's petition for rehearing to the Court of Appeals dated July 1, 1949, was denied, and it is apparent that the only purpose of the petition was to obtain a modification of the Appellate Court's decision so as to eliminate the portion thereof which directed this Court to grant a new trial. In conformance with the mandate, this Court on October 29, 1949, set aside the judgment and sentence entered herein and granted a new trial. I must assume, in view of the opinion of The Court of Appeals and its refusal to make the modification requested by defendant, that it determined that a new trial as to Counts I and III would not place defendant in jeopardy a second time in violation of his constitutional rights. The refusal of the Supreme Court to grant a writ of certiorari has also been called to my attention.

"Now, whether we designate the forms of verdict returned in this case as special or general verdicts, and there is approval by the United States Supreme Court of so-called special verdicts being submitted in criminal cases where several acts are pleaded in separate counts, Cramer v. United States, 325 U. S. 1, 36, Haupt v. United States, 330 U. S. 631, 641, we have a finding of the jury herein that the defendant, on the evidence submitted and under the instructions of the Court, was not guilty of certain acts of misbranding as charged in these two counts. Therefore, in determining the specifications of misbranding as alleged in these two counts which should now be submitted to a jury on a new trial, I have concluded that I should hold that the specifications of misbranding in Counts I and III, as to which the jury's finding herein was that of not guilty, should be eliminated, and they hereby are withdrawn from further consideration on the retrial. This holding is in accordance with the view of the Government's counsel, as expressed in their brief in the Supreme Court of the United States on the petition of the defendant for a writ of certiorari.

"It follows, therefore, that as to Counts I and III, the specifications of misbranding by false and misleading labeling, as alleged in each of said counts within the meaning of 21 U. S. C. § 352(a), will constitute the sole remaining charges of misbranding which will be tried on the new trial herein. Defendant was instrumental in obtaining a vacation of the verdicts returned on Counts I and III and the judgment entered thereon, and in view of the

elimination by withdrawal of the specifications of misbranding of which defendant was found not guilty in these two counts, I am of the opinion that the new trial as to the remaining specifications of misbranding therein will not be in violation of defendant's constitutional rights. Defendant's motion to dismiss, except to the extent and in the manner as indicated herein, will be, and is, denied.

"An exception is allowed."

On March 21, 1950, the defendant changed his original plea of not guilty to a plea of nolo contendere on counts 1 and 3 of the information, as limited by the court's decision of March 9, 1950. On March 22, 1950, the court imposed a fine of $1,000 without costs.

3063. Misbranding of Benzedrine Sulfate Tablets and sulfathiazole tablets. U. S. v. Samuel Price (Sam Price's Drug Store). Plea of nolo contendere. Fine, $500. (F. D. C. No. 28150. Sample Nos. 53329-K, 53896-K, 53906-K, 54125-K, 54130-K, 54321-K.)

INFORMATION FILED: April 5, 1950, Eastern District of Louisiana, against Samuel Price, trading as Sam Price's Drug Store, New Orleans, La.

INTERSTATE SHIPMENT: Between the approximate dates of October 16, 1947, and May 16, 1949, from the States of Pennsylvania and Michigan into the State of Louisiana.

ALLEGED VIOLATION: On or about June 13, July 13 and 20, and August 11 and 26, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into small bottles, and to be sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), the repackaged *Benzedrine Sulfate Tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (f) (1), the repackaged *Benzedrine Sulfate Tablets* bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 26, 1950. A plea of nolo contendere having been entered, the court imposed a fine of $500.

3064. Misbranding of nembutal capsules, Benadryl Capsules, thyroid tablets, Tuinal Capsules, and Benzedrine Sulfate Tablets. U. S. v. Alden M. Clifford (Nu-Way Stores). Plea of guilty. Fine, $150. (F. D. C. No. 28117. Sample Nos. 46088-K to 46092-K, incl., 61201-K.)

INFORMATION FILED: January 28, 1950, Western District of Missouri, against Alden M. Clifford, a partner in the partnership of Nu-Way Stores, Joplin, Mo.

INTERSTATE SHIPMENT: The drugs were shipped in interstate commerce into the State of Missouri prior to the dates of the sales of such drugs by the defendant, as hereinafter described.

ALLEGED VIOLATION: On or about July 11 and 12, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold to various